EXHIBIT A

to the Government of Puerto Rico's Second Amended Complaint
(Exhibit 1 to the Government of Puerto Rico's Letter Brief)

FEHB Program Carrier Letter
Experience-Rated HMO and Fee-For-Service Carriers

U.S. Office of Personnel Management
Healthcare and Insurance

Letter Number 2024-02

Date: January 25, 2024

FEHB [xx] PSHB [xx]

Fee-for-service [2] Experience-rated HMO [2] Community-rated HMO [n/a]

Subject: Pharmacy Benefits Management (PBM) Transparency Standards

This Carrier Letter clarifies Pharmacy Benefit Manager (PBM) Transparency Standards for fee-for-service (FFS) and experience-rated (ER) HMO Carriers.

In the event of a conflict between this letter and a prior FEHB Carrier Letter, this letter supersedes.

Background

OPM has included PBM standards in FEHB contracts since 2005 for FFS Carriers and 2008 for ER HMO Carriers. In 2011, new transparency standards were implemented for FFS Carriers, including requiring PBMs to base Carrier costs on negotiated price with network pharmacies or the actual acquisition cost for PBM-owned or affiliated pharmacies. Throughout the years, OPM has remained firmly committed to transparency standards regarding prescription drug benefits as an integral part of administering the FEHB Program. Due to the added layers of complexity related to PBMs' business practices over the years, OPM is reissuing this guidance.

These requirements regarding PBM transparency also apply to Medicare Employer Group Waiver Plans (EGWPs) offered to FEHB and PSHB enrollees and their family members.

PBM Transparency Oversight

FFS and ER HMO Carriers are required to adhere to the following principles to ensure appropriate oversight of PBMs.

- Carriers must have a robust set of mechanisms and processes, including detailed policies, audit standards, and terms to provide oversight of PBMs.
- Carriers must have full audit rights to all PBM network pharmacy contracts, claims data, manufacturer payments,[1] invoices, and clinical services coverage criteria.
- Carrier contracts with PBMs must not have terms which prohibit Carriers from determining who may conduct audits and frequency of audits.
- FFS and ER HMO Carriers with PBM contracts that are considered large provider agreements[2] must conduct audits of books and records directly related to drug payments and contract agreements at the contracting officer's discretion. Carriers must submit a summary of audit findings and corrective action plans, if applicable, to the contracting officer and copy OPMPharmacy@opm.gov starting no later than January 1, 2026.
- If the Carrier contracts with a third party to conduct an audit of a PBM, the Carrier must use independent auditors without conflicts of interest to conduct comprehensive audits.
- Carriers must have the authority to determine any terms involved in audits (except for the Federal Government audit entities audits), including contract compliance, pricing, financials, manufacturer payments, or other relevant details. This right would extend to any applicable subcontractors and vendors, including but not limited to rebate processors.
- Carriers must provide oversight of formulary management, including but not limited to any formulary changes involving hyperinflationary

[1] "Manufacturer payments" means any and all compensation, financial benefits, or remuneration the PBM or any third party receives from a pharmaceutical manufacturer for any dispensing or distribution channel, including but not limited to, discounts, credits, rebates (regardless of how categorized), market share incentives, chargebacks, commissions, administrative or management fees, patient assistance and any fees received for sales of utilization data to a pharmaceutical manufacturer.
[2] Federal Employees Health Benefits Acquisition Regulation: Large Provider Agreements, Subcontracts, and Miscellaneous Changes, 70 FR 31374 (2005).

concerns, mid-year changes, new-to-market drugs[3], brand drugs with generic equivalents available, and over-the-counter drugs.

- Contracts between PBMs and Carriers shall include clear details related to manufacturer payment schedules and fees generated from manufacturers.
- Carriers' transparency standards must include terms related to having access to information at each claim and aggregate level between PBMs and pharmacies (including PBMs and PBM-owned or affiliated pharmacies).
- Carrier contracts with PBMs must provide information related to all contractual terms, including but not limited to the clear definition of brand, generic, and specialty drugs, default discount guarantee for any new-to-market drugs, carve-out rights allowing the entity to obtain specialty drugs from other pharmacies, and drug-by-drug manufacturer payment for all drugs.
- PBM contracts must also clearly contain terms related to PBM-rebate aggregators, group purchasing organization arrangements, pricing methods for all pharmacy distribution channels (e.g., retail, mail, and specialty), refill protocols, meaningful performance guarantees, and network adequacy terms.
- All contracts, agreements, other documentation, or evidence related to the pharmacy benefit design and costs, including but not limited to invoices, receipts, and credits, that support amounts charged to the Carrier contract must be fully disclosed within 30 days of request without redaction to and must be auditable by the Carrier, OPM contracting officer, and the OPM OIG upon request.

Pass-Through Transparent Pricing[4]

FFS and ER HMO Carriers must ensure their PBMs adhere to the following transparent pricing standards. Additionally, Carriers must ensure that PBMs provide pass-through transparency for all pharmacy distribution channels. Pass-through transparent pricing standards do not apply to Medicare

[3] In this document, the term "drug(s)," it includes biological products. Biological products are regulated by the Food and Drug Administration (FDA) and are used to diagnose, prevent, treat, and cure diseases and medical conditions. Biological products are a diverse category of products and are generally large, complex molecules. *See* Biological Product Definitions, FDA.

[4] As defined in OPM's contracts with Carriers, "pass-through transparent pricing" means drug pricing in which the Carrier receives the full value of all discounts, rebates, credits or other financial guarantees or adjustments including any true up or reconciliation.

Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug (MA-PD) plans where the PDP or MA-PD sponsor, with which the Carrier contracts, bears the risk.

- The cost of drugs, products, and supplies filled by pharmacies not affiliated with the PBM shall be based on the negotiated price in each pharmacy agreement and the pass-through transparent pricing at the value of the pharmacy agreement for each drug plus a dispensing fee.
- The cost of drugs, products, and supplies filled by PBMs-owned or affiliated pharmacies shall be based on the actual acquisition cost, plus a dispensing fee and pass-through transparent pricing.
- PBMs must disclose all Maximum Allowable Cost lists[5] used for Carriers' pricing and provide the rationale for having more than one list.
- Carriers must have access to plan-specific net drug cost information (after manufacturer payments, network pharmacy discounts, PBM negotiated discounts, and any other discounts from any other sources) at each drug code level.
- The PBM must agree to disclose each fee to the Carrier and OPM.
- A PBM's administrative fee shall represent the PBM's sole source of profit. Any additional fees collected by the PBM for retail pharmacy transactions must be credited back to the Carrier.
- PBMs shall not charge Carriers more than the value of the PBM's negotiated discounts with each pharmacy in effect at the time of claim adjudication. True-ups to any pricing guarantees should be performed quarterly.
- Except for the costs associated with dispensing the drugs, a PBM shall not create additional markups for 340B[6] claims.
- Carriers must ensure that members are charged the lesser of the prescription price or applicable cost-share amount for prescription

[5] Maximum Allowable Cost (MAC) pricing is a payment model contractually agreed to in the marketplace by all participants. The model ensures that those purchasing health insurance benefits, including individual consumers, do not overpay for generic drugs. MAC pricing is designed to promote competitive pricing for pharmacies as an incentive for them to purchase less costly generic drugs available in the market, regardless of the manufacturer's list price, since manufacturers will charge different amounts for equally interchangeable generic drugs. *See* Maximum Allowable Cost (MAC) Pricing, available at AMCP.org.

[6] The 340B Program allows certain hospitals to buy outpatient drugs at discounted prices. To be eligible for the program, hospitals generally must treat a minimum percentage of low-income Medicare and Medicaid patients. Rosenberg, Michelle B. (May 11, 2023), 340B Drug Discount Program*: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19*. U.S. Government Accountability Office.

drugs. OPM considers the prescription price to be the drug's negotiated price plus dispensing fee or the cash price at the point of sale.

- PBMs must report their Actual Acquisition Cost for PBM-owned or affiliated pharmacy drugs dispensed at each claim and aggregate levels within six months of the quarter in which manufacturer payment was earned.
- All administrative and dispensing fees must be clearly attributable to retail, mail, specialty claims, clinical programs, and any other programs.

Pass-Through Transparent Manufacturer Payments

- FFS and ER HMOs Carriers must ensure their PBMs adhere to the following manufacturer payment transparency standards. Again, pass-through transparent manufacturer payments standards do not apply to Medicare PDPs or MA-PDs where the PDP or MA-PD sponsor, with which the Carrier contracts, bears the risk. PBMs shall disclose to Carriers all contracts with drug manufacturers[7] and intermediary contracting organizations.
- PBMs must disclose to Carriers drug manufacturer payment information at each claim and at aggregate levels, all sources of revenue or other consideration, including all sources of manufacturer payments for each business segment for that contract year, and the attribution of administrative fees to claims and service.
- PBMs must pass through to Carriers one hundred percent (100%) of current, past, and future drug manufacturer payments in any form, regardless of whether the applicable benefit is billed as pharmacy or medical.
- PBMs shall pass through to Carriers one hundred percent (100%) of manufacturer payments, discounts, bulk purchase/volume incentives, commissions, credits, price concessions, or any other financial benefits received from drug wholesalers, rebate aggregators, and group purchasing organizations related to the cost of drugs filled by PBM-owned or affiliated pharmacies.
- Rebate aggregators or group purchasing organizations that are owned by or affiliated with the PBM are required to pass through to Carriers 100% of the manufacturer payments collected from drug manufacturers.

[7] Drug manufacturers do not include rebates aggregators, distributors, wholesalers, or other entities that do not manufacture drugs.

- Entities owned by or affiliated with the Carrier or PBM that manufacture, co-brand, co-license, commercialize and/or co-produce or distribute drugs are required to pass through 100% of the manufacturer payments to Carriers.
- PBMs must pass through to Carriers all drug inventory purchasing discounts associated for retail, mail order, and specialty drugs.
- Any credit that the PBM receives back from any pharmacies related to the processing of a Carrier's prescription drug benefits should be deducted from the cost of drugs since the administrative fees shall cover all administrative expenses as the sole source of profit.
- PBMs must pass to Carriers one hundred percent (100%) of fees received from a manufacturer for formulary placement or access.
- For any utilization management and educational programs/initiatives that PBMs implement, Carriers must require full disclosure of any resultant revenue and have policies in place to ensure Carriers' approval prior to implementation.

Additionally, Carriers should include mechanisms aimed at managing costs, such as requiring PBMs to perform market checks at least annually during the contract term. A contract between a Carrier and a PBM shall not exceed 3 years without re-competition unless the contracting officer approves an exception.

OPM will decline any arrangements which may manipulate the prescription drug benefit design or incorporate any programs such as copay maximizers, copay optimizers, or other similar programs as these types of benefit designs are not in the best interest of enrollees or the Government.

To provide effective and affordable prescription drug benefits, Carriers must exercise due diligence, implement these standards, and use transparent pass-through pricing and manufacturer payments when contracting with PBMs. Carriers are required to apply the transparency standards mentioned above with current PBM contractors and subcontractors.

Conclusion

OPM remains committed to the highest PBM transparency standards in administering the FEHB Program and requires review and incorporation of these standards in PBM contracting arrangements.

For questions about this Carrier Letter, please contact OPMPharmacy@opm.gov and copy your contracting officer.

Sincerely,

Laurie Bodenheimer
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